payment or reimbursement from Eximbank for such expenses.

[FR Doc. 94-14715 Filed 6-16-94; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 821

Delegations of Authority and Organization; Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to general redelegations of authority from the Associate Commissioner of Regulatory Affairs to certain FDA officials in the Center for Devices and Radiological Health (CDRH). The redelegation provides these officials with authority to grant or deny certain citizen petitions for exemption or variance from medical device tracking requirements. This action is being taken to facilitate expeditious handling of citizen petitions. FDA is also issuing a conforming amendment to the medical device tracking regulations to make the regulations consistent.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4765, or Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending the regulations in § 5.31 *Petitions under part 10* (21 CFR 5.31) by granting the authority to the Director and Deputy Directors, CDRH, and the Director, Office of Compliance (previously known as the Office of Compliance and Surveillance), CDRH, to issue responses to citizen petitions submitted in accordance with §§ 10.30 and 821.2(b) (21 CFR 10.30 and 821.2(b)) requesting an exemption or variance from the provisions of part 821 concerning medical device tracking requirements. FDA is making a conforming amendment to 821.2(b), which currently lists only the Director, Office of Compliance and Surveillance, CDRH, as authorized to issue such responses, to add the Director and Deputy Directors, CDRH.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

This document is issued as a final rule because the rulemaking requirements in 5 U.S.C. 553 do not apply to rules of agency organization, procedure, or practice.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 821 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701-1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1, 300aa-25, 300aa-27, 300aa-28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660 (42 U.S.C. 300aa-1 note).

2. Section 5.31 is amended by adding new paragraph (g) to read as follows:

§ 5.31 Petitions under part 10.

* * * * *

(g) The Director and Deputy Directors, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

3. The authority citation for 21 CFR part 821 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 515, 518, 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, and 374).

4. Section 821.2 is amended by revising the second sentence in introductory text of paragraph (b) to read as follows:

§ 821.2 Exemptions and variances.

* * * * *

(b) * * * The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. * * *

* * * * *

Dated: June 13, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94-14855 Filed 6-16-94; 8:45 am]
BILLING CODE 4160-01-F

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name from Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., to Ohmeda Pharmaceutical Products Division Inc.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1646.

SUPPLEMENTARY INFORMATION: Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., Liberty Corner, NJ 07938-0804, has informed FDA of a change of sponsor name from Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., to Ohmeda Pharmaceutical Products Division Inc. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "Anaquest, Inc., A Subsidiary of BOC Health Care, Inc." and by alphabetically adding a new entry for "Ohmeda Pharmaceutical Products Division Inc., Liberty Corner, NJ 07938–0804.....010019"; and in the table in paragraph (c)(2) in the entry for "010019" by removing the sponsor name "Anaquest, Inc., A Subsidiary of BOC Health Care, Inc." and by adding in its place "Ohmeda Pharmaceutical Products Division Inc."

Dated: June 9, 1994.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 94–14709 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Boehringer Ingelheim Animal Health, Inc., to Phoenix Scientific, Inc.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belth Hwy., St. Joseph, MO 64506–2002, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 99–169 for Oxytocin Injection to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO, 64506–0457. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) and in 21 CFR 522.1680(b) to reflect the change of sponsor.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Phoenix Scientific, Inc." and in the table in paragraph (c)(2) by numerically adding a new entry for "059130" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.C Box 6457, St. Joseph, MO 64506–0457	059130
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
059130	Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1680 [Amended]

4. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing "000010" and "and 058639" and by adding "058639, and 059130" before the word "in".

Dated: June 9, 1994.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 94–14708 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fort Dodge Laboratories. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Larry D. Rollins, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, Fort Dodge, IA 50501, is the sponsor of ANADA 200–102, which provides for the use of a generic gentamicin solution (100 milligrams/milliliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

ANADA 200–102 for Fort Dodge Laboratories' gentamicin sulfate solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin Solution (100 mg/mL gentamicin) in